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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA et al., *ex rel.* JESSICA PENELOW AND CHRISTINE BRANCACCIO,
 	
   Plaintiffs,
 	
   v.
 	
JANSSEN PRODUCTS, LP
 	
   Defendant.
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		CASE NO. 12-7758 (MAS)(LHG)
		
		Motion Date: March 15, 2021
		
		ORAL ARGUMENT REQUESTED

DEFENDANT JANSSEN PRODUCTS, LP'S MEMORANDUM OF LAW
IN SUPPORT OF MOTION TO EXCLUDE EXPERT TESTIMONY OF
<u>ISRAEL SHAKED AND IAN DEW</u>

TABLE OF CONTENTS

TABLE OF AUTHORITIES

I.   **INTRODUCTION AND SUMMARY OF ARGUMENT**

A physician's decision to prescribe a particular medication to treat an HIV patient is a complex medical judgment based on multiple factors that vary for each patient. To prove their claims under the False Claims Act ("FCA"), Relators must show that Janssen's alleged misleading marketing *caused* physicians to prescribe Prezista and Intelence "off-label"[1] for their HIV patients thereby *causing* false claims to be submitted to the government. This requires Relators to establish that the alleged misleading marketing caused a physician's prescription, as opposed to the many clinical considerations that inform a physician's decision.

With no direct evidence from any physicians, Relators attempt to fill this void with expert opinions purporting to find general causation from data analyses performed by a statistician, Professor Israel Shaked ("Shaked"), assisted by data analyst, Ian Dew ("Dew"). But, these data analyses show nothing more than correlation, not causation. Neither expert considered any evidence from the physicians who made the prescribing decisions in evaluating the question of why they wrote Prezista and Intelence prescriptions for their patients. Instead, Shaked and Dew used Medicare claims data, which lack any information bearing on the reason for the prescription, to construct a flawed statistical model not generally accepted to make purported causal conclusions. The resulting opinions are unreliable because the statistical model yields nothing more than simple correlations that fail to account for the impact of confounding factors, and the assumptions used to define the key variables are unsupported and contradicted

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[1] While Relators imply that there is something improper about "off-label" prescriptions, the law permits a physician to prescribe drugs for unapproved, or off-label, uses if the physician believes it is in the best interests of the patient based on her independent medical judgment. *See, e.g., In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 240 (3d Cir. 2012) ("Prescription drugs frequently have therapeutic uses other than their FDA-approved indications. . . . Because the FDCA does not regulate the practice of medicine, physicians may lawfully prescribe drugs for off-label uses.").

by the facts of this case. For at least three independent reasons, the opinions of Shaked and Dew should be excluded.

First, Shaked employed a simple two variable correlation analysis to find that a group of physicians assumed to have been exposed to Janssen's alleged off-label marketing ("influenced") prescribed Prezista and Intelence off-label at a higher rate than a group of physicians who were assumed not to have been exposed ("non-influenced"). By limiting his analyses to just these two variables—exposure to Janssen's alleged off-label marketing and off-label prescription rate—Shaked failed to control for the multitude of confounding factors that impact a physician's independent medical judgment in making prescribing decisions. Shaked ignored this reality to make the unwarranted and legally improper leap that it is "virtually certain" that Janssen's alleged improper marketing *caused* "influenced" physicians to prescribe Prezista and/or Intelence off-label from 2006 through 2014. Courts reject expert causation opinions based on statistical correlations that fail to account for obvious confounding factors, and this Court should likewise preclude Shaked's proffered causation opinions as unreliable because they are based on a methodology not generally accepted for making causal inferences.

Second, even if a statistical correlation were sufficient to support a causal inference, which it is not, Shaked and Dew also relied on flawed assumptions from Relators' counsel to define the two key variables, further undermining the reliability of their causation opinions. Specifically, counsel defined the group of "influenced physicians" based on whether a physician received a single sales call, attended a single speaking event, or spoke once on behalf of Janssen over a nine-year period. These supposed proxies for receiving and acting on alleged improper marketing from Janssen are not supported by the facts and are directly contradicted by one of the Relators. Further, counsel and Dew artificially inflated the off-label prescribing rates

-2-

for influenced physicians by directing that a patient's "lifelong" off-label prescriptions be attributed to the initiating influenced physician, even when the patient subsequently switched to a non-influenced physician for continuing care. As a result, Shaked and Dew's calculation of the off-label rate for influenced physicians included off-label prescriptions those physicians did not write. Both of these assumptions improperly distorted the variables measured in Shaked's correlation analysis, rendering his results and opinions unreliable.

Finally, based on his general causation opinion that Janssen's alleged improper promotion caused "influenced" physicians to prescribe Prezista and Intelence off-label at a higher proportion than non-influenced physicians, Shaked then applied the same flawed assumptions in his damages model to opine that *every* alleged off-label prescription written by or attributed to an influenced physician should be considered a false claim caused by Janssen resulting in damages to the government. Because this methodology is flawed and these assumptions are unsupported by the facts of the case, Shaked's categorical identification of false claims and resulting estimates of damages caused by Janssen are unreliable and should be precluded.

For the reasons set forth above, Shaked and Dew's proffered expert opinions and analyses relating to any causal connection between Janssen's alleged off-label marketing activity and prescriptions written by influenced physicians should be excluded in their entirety, and both Shaked and Dew should be precluded from testifying on any related topics at trial.

II.   BACKGROUND

A.   Israel Shaked

1.   Shaked's experience is limited to areas of finance and business administration, and he has never before analyzed the cause of physician prescribing decisions.

Shaked's academic and professional background and experience are deeply rooted

in matters of finance, business administration, bankruptcy valuations, and other business-related topics. He has a Doctor of Business Administration Degree from Harvard Business School, and has been a professor of finance and economics for many years at Boston University's Questrom School of Business, where he currently teaches a class on corporate finance and valuation. Chuderewicz Decl., Ex. A (Nov. 27, 2019 Expert Report of Israel Shaked) at Ex. 1 (Curriculum Vitae); Chuderewicz Decl., Ex. B (8/28/2020 Shaked Dep. Tr.) at 26:10. Shaked also is the co-founder and managing director of The Michel-Shaked Group, which primarily provides expert testimony for litigation matters on various financial topics, with business valuation being "the bread and butter of the firm." Ex. A at Ex. 1; Ex. B at 54:4-7, 54:22-55:15.

Shaked has never evaluated, analyzed, studied, written about, or had any experience in the area of evaluating what factors might *cause* a physician to prescribe a particular medication for an individual patient. Ex. B at 35:16-25, 45:9-15, 46:10-14, 49:18-22, 65:5-12, 69:11-15. Similarly, he has never done any research on the impact of marketing by pharmaceutical companies on physicians' prescribing decisions, let alone any general research relating to the impact of any marketing in any industry on the audience to whom the marketing was directed. *Id.* at 44:16-20, 68:4-10. In short, the assumptions provided by Relators' counsel and the resulting methodology have never been used by Shaked in any of his litigation engagements or submitted for peer review to any scientific publications.

2.   Summary of Shaked's proffered opinions

(a)   <u>General causation</u>: **Shaked opines that *alleged improper promotion* caused influenced physicians to prescribe Prezista and Intelence off-label at a higher rate than non-influenced physicians.**

Shaked opines that it is "virtually certain" that Janssen's alleged improper promotion "caused" influenced physicians to prescribe higher proportions of "off-label" Prezista

and Intelence prescriptions than non-influenced physicians. Ex. A ¶ 16.[2] In forming his opinions, Shaked did not review any medical records for patients who were prescribed these medications, nor did he speak with or review any information or testimony from the prescribing physicians who made those decisions. Ex. B at 111:20-25, 112:8-15. Rather, Shaked's general causation opinions are based solely on statistical analyses he performed using inputs provided by Relators' counsel and Relators' expert data analyst, Dew. *E.g.*, *id.* at 90:20-23 ("The final approval, what gets into the analysis, is mine. Assuming certain of the decisions – for example, medical ... was not mine[.]"); *id.* at 89:18-22 ("[Dew] knows how to retrieve data whenever needed, and in certain aspects, we consulted with him as well as with the counsel on what is appropriate selection criteria.").

Specifically, to support his opinion that alleged improper promotion "caused" a higher proportion of off-label claims to be written, Shaked presents several correlation analyses that purport to show that "influenced" physicians were more likely to prescribe Prezista and Intelence off-label than "non-influenced" physicians. *E.g.*, Ex. A ¶ 106. A correlation analysis "measures the association between two variables," here, the association between receiving the alleged off-label messaging (on the one hand) and the corresponding "off-label" prescribing rates (on the other). *See* Federal Judicial Center and National Research Council of the National Academies, *Reference Manual on Scientific Evidence* 262 (3d ed. 2011).[3]

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[2] Shaked has produced three reports in this matter: (1) Expert Report (with Errata); (2) Rebuttal Expert Report; and (3) Supplement to the Rebuttal Expert Report. Only the Expert Report provides affirmative opinions on causation and damages related to Relators' off-label promotion and kickback claims. *See* Ex. A ¶¶ 13-16. Neither his Rebuttal nor his Supplement alter the assumptions, methodology, or ultimate causation opinions provided in his Expert Report.

[3] Professor Shaked compares the average rate of off-label prescriptions between "influenced" and "non-influenced" as a whole (Ex. A ¶¶ 98-106, Analysis 6), and between sub-categories of "influenced" and "non-influenced," specifically, speaker event attendees and non-attendees (*id.*

To define which physicians were "influenced"—the first variable being measured—Relators' counsel directed Shaked to assume that any one of three different single contacts between a physician and Janssen was sufficient. Ex. A ¶ 25 ("I have been asked by Relators' Counsel to assume Janssen's liability under the False Claims Act[.]"); Ex. B at 175:1-16 (confirming "influenced" is "based on consultation with counsel" because "liability in this case is basically assumed"). Specifically, counsel instructed Shaked that physicians became "influenced" by allegedly hearing off-label information in one of three ways: (1) receiving a *single* sales call from a Janssen sales representative, (2) attending a *single* speaking event, or (3) speaking at a *single* speaking event, at any point in time from June 2006 through the end of 2014. Ex. A ¶ 47. The definition of "influenced" further assumes that *every* sales call and *every* speaking event between June 2006 and the end of 2014 included *all* the same alleged improper messages at issue in this case about both Prezista *and* (from January 2008 onward) Intelence. Ex. B at 178:17-179:6, 181:5-10. Neither Shaked, Dew, nor Relators' counsel made any effort to confirm with any physician that he or she improperly received any alleged off-label information from Janssen.

In calculating physicians' off-label rates—the second variable being measured—Shaked and Dew proceeded under another instruction from Relators' counsel. Ex. B at 220:8-10. They were told to attribute a patient's lifelong "off-label" Prezista and Intelence prescriptions to the physician who first prescribed the medication, ignoring whether that initiating prescriber continued to treat the patient or actually wrote any of the subsequent prescriptions. *E.g.*, Ex. A ¶ 101; Ex. B at 220:22-221:12. Shaked therefore assumed that the

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¶¶ 127-132, Analysis 9), and speakers and non-speakers (*id.* ¶¶ 136-141, Analysis 11), and he also compared the number of marketing contacts and "off-label" prescriptions (*id.* ¶¶ 107-120, Analysis 7).

initiating prescriber is the only physician who exercised any independent medical judgment

when determining a patient's HIV ongoing medication regimen. *See* Ex. B at 217:13-22,

218:15-21. Because "influenced" physicians initiated significantly more prescriptions than

"non-influenced" physicians, this assumption distorted the off-label rates calculated by Shaked.

> **(b)** **General causation**: Shaked opines that *speaker payments* caused physicians to prescribe Prezista and Intelence.

Shaked also opines that it is "virtually certain" that Janssen's payments to

speakers "caused" Prezista and Intelence prescriptions to be written. Ex. A ¶ 15. To support his

opinion that speaker payments "caused" prescriptions to be written, Shaked similarly presents

correlation analyses that purport to show that speakers were more likely than non-speakers to

prescribe Prezista and Intelence. *E.g.*, *Id.* ¶ 97. Speaker payments and speaker prescriptions

(dollar amounts) are the two variables whose association is being measured in Shaked's

correlation analyses. *See Reference Manual on Scientific Evidence* at 262.[4]

> **(c)** **Specific causation and damages**: Shaked opines on economic damages caused by *alleged improper promotion.*

Following his general causation finding, Shaked returns to counsel's definition of

"influenced" physicians and direction to attribute a patient's lifelong off-label prescriptions to

the initiating prescriber to identify categories of false claims, or "off-label claims," and estimate

the specific damages *caused* by Janssen's alleged improper promotion. Ex. A ¶¶ 41-48. With

direction from counsel and Dew, Shaked defined categories of off-label claims using "four

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[4] Specifically, Shaked compared the average proportion of Prezista and Intelence prescriptions to all antiretroviral ("ARV") prescriptions for speakers and non-speakers (Ex. A ¶¶ 91-97, Analysis 5), and also compared the average annual prescriptions (in dollars) to the total amount of speaker compensation to purportedly show that speakers who received more compensation prescribed more Prezista and Intelence than speakers who received less compensation (*id.* ¶¶ 82-90, Analysis 4).

measuring approaches:" Prezista Lipid-Neutral,[5] Prezista Treatment-Naïve, Intelence Treatment-

Naïve,[6] and Intelence Once-Daily Dosing off-label claims.[7] *Id.* ¶¶ 41-45.

For Prezista Lipid-Neutral and Prezista/Intelence Treatment-Naïve claims,

Shaked opines that his general causation finding means that Janssen's alleged marketing caused

all prescriptions for patients whose *first* Prezista or Intelence prescription was "off-label" *and*

was written by an "influenced" physician from the launch of Prezista/Intelence through the end

of 2014 (or through September 2008 for Prezista Treatment-Naïve). *Id.* ¶¶ 47-48. Again, these

opinions estimating the alleged specific damages caused by Janssen are dictated solely by the

assumptions taken from counsel.

For Intelence Once-Daily Dosing claims, Shaked estimates damages (through

Dew's work) by applying the percentage of once-daily Intelence claims in each quarter, across

all payer types (government and non-government), based on the produced pharmacy dispensing

data, to the total Intelence reimbursements in that quarter (which includes those based on

prescriptions written by both "influenced" and "non-influenced" prescribers). *Id.* at Appendix A.

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[5] Prezista Lipid-Neutral "off-label" claims are based *solely* on identifying a lipid-regulating medication *or* lipid-related diagnosis in the CMS claims data *prior* to a patient's first Prezista prescription. Ex. A ¶ 42; Ex. B at 98:21-99:3, 120:2-6 (Lipid-Neutral – "I rely on Ian Dew[.]").

[6] Prezista Treatment-Naïve (only June 2006 – Sept. 2008) and Intelence Treatment-Naïve "off-label" claims are based *solely* on identifying patients whose first Prezista or Intelence claim was not preceded by another (non-Prezista/non-Intelence) ARV claim *and* was at least 90 days after the first claim of *any* kind in the CMS data for a given patient. Ex. A ¶¶ 43-44; Ex. B at 164:7-20 (Treatment-Naïve – "[W]e discuss it with Ian. We discuss it with counsel.").

[7] Intelence Once-Daily Dosing "off-label" claims are based *solely* on estimates, specifically, using dispensing data produced by selected pharmacies to estimate the percentage of prescriptions with once-daily dosing instructions out of all Intelence prescriptions observed in that data. Ex. A ¶¶ 45-46; Ex. B at 164:24-165:19 (Once-Daily Dosing – "So we actually ask Ian to look at this[.]").

**(d)   Specific causation and damages: Shaked opines on
economic damages resulting from *speaker payments.***

Shaked also was instructed by Relators' counsel to assume that *all* speaker

payments by Janssen between June 2006 and the end of 2014 were improper. Ex. A ¶ 38

("Again, I assume Janssen's liability[.]"); Ex. B at 177:17-18 ("I was requested to assume that all

amounts paid to speakers are improper[.]"); *id.* at 79:9-14 ("For speakers, kickback is

straightforward. Once they got paid, if plaintiff prove in court that it was aimed to induce

prescribing, then everything that they wrote after that is – is part of the damages, independent of

any way they would have done it[.]"). Using this instruction from counsel, Shaked calculates

damages stemming from Janssen's alleged improper speaker payments as *all* government

reimbursements for Prezista and Intelence prescriptions written by speakers after receiving their

first payment through the end of 2014, regardless of whether that speaker was the initiating

prescriber and irrespective of when a speaker received his or her last speaker payment. Ex. A ¶

40; Ex. B at 180:3-4 ("For the speakers, doesn't have to initiate."); *id.* at 230:19-23 (confirming

no analysis of time between last speaking event and subsequent prescriptions).

B.   Ian Dew

1.   Dew's experience is limited to data processing and analytics.

Dew is an analyst with a private consulting firm who has for many years worked

with healthcare-related data to "basically crunch numbers or develop methodologies to facilitate

crunching numbers" to support litigation, as he has done here, as well as investigations.

Chuderewicz Decl., Ex. C (3/3/2020 Dew Dep. Tr.) at 35:24-36:8; *see also* Chuderewicz Decl.,

Ex. D (January 31, 2020 Rebuttal Report of Ian M. Dew) at Attachment A (Resume).

Dew did not review any patient medical records or direct evidence from

physicians in this matter. Ex. C at 90:10-15, 90:23-25. Like Shaked, Dew has never offered an

expert opinion on the *cause* of a prescribing decision, nor has he previously provided any data

analyses that were used to support such an opinion. *Id.* at 42:8-12, 43:2-5 ("[E]stablishing a

cause/effect relationship is – is not necessarily within the scope of my work and I don't recall

that I've done that.").

2.   Dew's assistance to Shaked.

Dew does not offer any independent opinions in this matter. *E.g.,* Ex. C at 138:7-

8 ("I'm not making an opinion as to the off-label or not in my work."). He produced: (1) a

Description of Methodology, *see* Chuderewicz Decl., Ex. E (Description of Methodology),

which explains his data analyses in this matter and was incorporated by Shaked into his Expert

Report as part of the documents considered in forming his opinions; and (2) a Rebuttal Expert

Report, which provides further details and rationale in support of the Methodology.

In Shaked's Expert Report, he states: "In arriving at my conclusions, I relied on

Ian Dew for analytical support." Ex. A ¶ 17. Shaked further explains that he "utilized Mr. Dew

to query databases of ADAP, Medicaid and Medicare based on information [he] requested" and

the "datasets that Mr. Dew relied upon are described" in his Methodology. *Id.* at 7 n.6. To the

extent Dew offers any opinions at all, they are only in support of, and inextricably tied to, the

work he performed for Shaked. *E.g.*, Ex. C at 160:14-15 ("[W]hat I'm doing is I'm filtering

claims according to criteria[.]"). Consequently, if the Court excludes Shaked's opinions (as it

should for the reasons set forth more fully below), Dew's opinions also should be excluded.

III.   ARGUMENT

A.   Shaked's general causation opinions relating to "off-label" promotion *and* speaker payments should be excluded because they are based on an *unreliable* methodology for assessing causation.

Shaked's statistical analyses are inadequate to bridge the gap between a simple,

two-variable correlation and the more rigorous scientific standards necessary to support a reliable

opinion on causation. Shaked's causal conclusions are, as he confirmed during his deposition,

based solely on measuring the correlation between just two variables. *See* Ex. B at 291:13-17.

But "correlation does not equal causation." *Norris v. Baxter Healthcare Corp.*, 397 F.3d 878,

885 (10th Cir. 2005). Rather, "inferring causation is much more complicated than simply

observing correlation, and the former should not be confused for the latter." *Wannall v.

Honeywell Int'l, Inc.,* 292 F.R.D. 26, 42 (D.D.C. 2013) ("When A is correlated with B, it could

be that A causes B, but it could also be that B causes A, or that A and B are both the

consequences of a common cause, among other possibilities."). And, there is no legal authority

that a correlation analysis can be sufficient grounds to support an expert opinion on the causal

connection between a pharmaceutical company's marketing activities and physicians'

prescribing decisions. Because statistical correlations are not generally accepted for assessing

the complex question of causation, the methodology Shaked used to form his causation opinions

is unreliable, and, as a result, his opinions must be excluded.

> **1.   Correlation analyses are not generally accepted methods for
> assessing causation.**

An expert witness may only "'testify in the form of an opinion or otherwise if,'

inter alia, 'the testimony is the product of reliable principles and methods[.]'" *In re: Zoloft

(Sertraline Hydrochloride) Prods. Liab. Litig.*, 858 F.3d 787, 792 (3d Cir. 2017) (quoting Fed. R.

Evid. 702). When assessing the reliability of an expert's methods, courts consider whether the

method is generally accepted in the relevant field. *Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 152

(3d Cir. 1999) (instructing district courts to be guided by "whether the technique has been

generally accepted in the proper scientific community").

Shaked relies solely upon simple statistical correlations to support his opinion that

one specific factor—Janssen "influence" or speaker payments—*caused* physicians to prescribe

Prezista or Intelence. The generally accepted methods by which statistical studies might serve as

an appropriate basis to potentially demonstrate causation are well-established in the scientific

community, and simple two-variable comparisons are not sufficient.

The *Reference Manual on Scientific Evidence*, for example, provides an overview

and hierarchy of the generally accepted types and designs of studies used to investigate and

evaluate causation. *Id.* at 217 (Reference Guide on Statistics, section II.A, entitled "Is the Study

Designed to Investigate Causation?").[8] As the *Reference Manual* explains, a "good study design

compares outcomes for subjects who are exposed to some factor (the treatment group) with

outcomes for other subjects who are not exposed." *Id.* at 218-19. Here, Shaked has attempted to

compare prescribing practices (the outcomes) for physicians who allegedly were exposed to

Janssen's assumed improper marketing or received speaker payments (the treatment groups) with

outcomes for other physicians who were not exposed to the alleged off-label promotion or who

were not speakers.

At the top of the hierarchy of studies used to investigate causation are *randomized

controlled experiments*, which "are ideally suited for demonstrating causation." *Id.* at 218. In

these experiments, "investigators assign subjects to treatment or control groups *at random*." *Id.*

at 220 (emphasis added). It is the investigators who "decide which subjects will be exposed and

which subjects will go into the control group." *Id.* at 219. Given that the investigators assign the

subjects at random, the "groups are therefore likely to be comparable, except for the treatment."

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[8] The *Reference Manual on Scientific Evidence* "is formulated to provide the tools for judges to manage cases involving complex scientific and technical evidence. It describes basic principles of major scientific fields from which legal evidence is typically derived[.]" *Id.* at xv; *see, e.g.*, *In re Diet Drugs Prods. Liab. Litig.*, MDL Dkt. No. 1203, 2001 U.S. Dist. LEXIS 1174, at *40-41 (E.D. Pa. Feb. 1, 2001) (citing *Reference Manual* in support of court's decision to exclude an expert who had failed to account for confounding factors in determining the cause of a disease).

Id. at 220.

Shaked's analyses cannot, by definition, be considered randomized controlled experiments because *he* did not decide which physicians would receive a sales call, attend a speaking event, or speak at a speaking event—those decisions were made in the first instance by Janssen and the physicians. During his deposition, Shaked surprisingly claimed that he had in fact performed a randomized controlled experiment. Ex. B at 262:2-5. But, when pressed, Shaked confirmed that the essential element for such an experiment—*his* random selection of who would be exposed to the treatment (promotion or speaking payments)—was missing. *E.g.*, *id.* at 263:18-21 ("I say I was one step ahead because I did not need to randomize. The two groups that got treatment and not treatment are already were given to us."); *id.* at 266:20-24 ("[T]he decision was made by Janssen. They decided who gets the treatment, who doesn't get the treatment."). Shaked's own testimony revealed that the analyses he performed here were not randomized controlled experiments. Additionally, as discussed above, the treatment group designated as "influenced" physicians was selected by counsel. This is not randomization in any sense of the term, and nothing Shaked says can change that. *See, e.g.*, *Zeller v. J.C. Penney Co.*, No. 05-2546, 2008 U.S. Dist. LEXIS 25993, at *14 (D.N.J. Mar. 31, 2008) ("'[N]othing . . . requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert.'") (citation omitted).

The next step down in the hierarchy of scientific evidence are *observational studies. Reference Manual* at 217. The "bulk of the statistical studies seen in court are observational, not experimental." *Id.* at 220. Unlike controlled experiments, in observational studies, "the subjects themselves choose their exposures." *Id.* at 219. Based on his own testimony, Shaked's analyses are akin to observational studies. While observational studies,

such as Shaked's correlation analyses, "can establish that one factor is *associated* with another,"

there is work "needed to bridge the gap between association *and* causation." *Id.* at 217-18

(emphasis added). That work includes consideration of potential "confounding" factors:

> Because of self-selection, the treatment and control groups are
> likely to differ with respect to influential factors other than the one
> of primary interest. (These other factors are called lurking
> variables or confounding variables.)
> . . . .
>
> [A] confounding variable may be correlated with the independent
> variable and act causally on the dependent variable. . . . The
> confounder—not the independent variable—could therefore be
> responsible for differences seen on the dependent variable.

Id. at 219 & n.17.[9] As the *Reference Manual* explains, "[c]onfounding remains a problem to

reckon with, even for the best observational research." *Id.* at 219. Therefore, the *Manual*

counsels courts to ask the following questions whenever assessing whether causal inferences

may be drawn from observed correlation:

- How did the subjects come to be in treatment or in control groups?
- Are the treatment and control groups comparable?
- If not, what adjustments were made to address confounding?
- Were the adjustments sensible and sufficient?

Id. at 222. Shaked agrees in theory, testifying that: "[c]onfounding factors are factors that might

be intervening factors explaining the results[.]" Ex. B at 256:22-25. Indeed, *Statistical*

Techniques in Business & Economics—the textbook Shaked cites as the source of the statistical

terminology used in his report—warns of reading too much into the correlation between two

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[9] As described above, the "treatment" group (influenced physicians) was not only self-selected in
the first instance by Janssen's decisions to call on, invite to attend an event, or pay to speak at an
event, and each physician's agreement to the same, but the group also was self-selected by
Relators' counsel.

variables: "What we can conclude when we find two variables with a strong correlation is that

there is a relationship between the two variables, not that a change in one causes a change in the

other." Douglas A. Lind et al., *Statistical Techniques in Business & Economics* 465 (11th ed.

2002).

2. Shaked's correlation analyses fail to account for confounding factors that may affect physicians' prescribing decisions.

Shaked performs none of the requisite work to "bridge the gap" between

correlation, on the one hand, and causation, on the other hand. His analyses fail to account for

any potential confounding factors in the complex decision-making process by which a

physician—relying on professional training, treatment guidelines, clinical trial results, medical

literature, and first-hand experience—weighs multiple patient specific factors in arriving at the

appropriate prescription medication to treat HIV. And, yet, Shaked still, based on nothing more

than showing a correlation between two variables, attempts to offer the causal opinions that

receiving alleged off-label messaging or speaker payments *caused* physicians to subsequently

prescribe Prezista and/or Intelence.

In fact, the treatment and control groups analyzed by Shaked differ in meaningful

ways. Using the same data that was available to Shaked, Janssen's expert, Dr. Anupam Jena,

identified the indisputable factual differences between the two groups of prescribers being

analyzed ("influenced" and "non-influenced" physicians, speakers and non-speakers).

Chuderewicz Decl., Ex. F (Jan. 31, 2020 Expert Rebuttal Report of Dr. Anupam B. Jena, MD,

PhD) at Exs. 3, 9. For example, 49% of "influenced" physicians were infectious disease

specialists (the specialty that encompasses HIV treatment), as opposed to only 12% of the "non-

influenced" physicians; "influenced" physicians had an average of 7 years of experience

prescribing ARV medications, as opposed to an average of only 3 years for the "non-influenced"

-15-

physicians; "influenced" physicians also on average prescribe 21 different non-Janssen ARV

medications, compared to an average of only 7 by the "non-influenced" physicians; and 83% of

the "influenced" physicians initiated a patient on Prezista or Intelence during the relevant time

period (17% did not initiate any patients), compared to only 34% of the "non-influenced"

physicians (66% did not initiate any patients). Ex. F at Ex. 3.

These obvious differences show that physicians in Shaked's "influenced" group

have demonstrably different backgrounds and practices than those in the "non-influenced" group.

To even attempt to make any reliable inferences about the *cause* of the prescribing decisions

made by these two groups of physicians, Shaked would be required to make adjustments to his

analyses to make the two groups comparable. But he did not. *See, e.g.*, *People Who Care v.

Rockford Bd. of Educ.,* 111 F.3d 528, 537-38 (7th Cir. 1997) (concluding that "a statistical study

that fails to correct for salient explanatory variables, or even to make the most elementary

comparisons, has no value as causal explanation and is therefore inadmissible in federal court").

In his report, Shaked compares, for instance, the average "off-label" rates of the

"influenced" group (5,177 physicians with an average off-label rate of 22.3%) and the "non-

influenced" group (19,998 physicians with an average off-label rate of 11.2%). Ex. A ¶¶ 103-

105. Based on the difference in rates between these two groups, Shaked concludes that it is

"virtually certain" that Janssen's "marketing activities and Speaker program" were *the* cause of

that difference. *Id.* ¶ 106. But, exposure to Janssen's "marketing activities and Speaker

program" is only *one factor* that differentiates these two groups. The problem of confounding,

as the *Reference Manual on Scientific Evidence* advises, must be addressed before any reliable

causal inferences can be made—"association is not causation." *Id.* at 221. Are the 5,177

physicians in the "influenced" group (treatment group) and the 19,998 physicians in the "non-

influenced" group (control group) comparable? If, as explained above, they are not, what

adjustments were made to address confounding? The answer here is none. *See Sheehan v. Daily*

Racing Form, 104 F.3d 940, 942 (7th Cir. 1997) (finding expert's statistical study to be

inadmissible for failure "to make any adjustment for [other] variables . . . [and] equating a simple

statistical correlation to a causal relation . . . indicates a failure to exercise the degree of care that

a statistician would use in his scientific work, outside of the context of litigation"); *AstraZeneca*

LP v. Tap Pharm. Prods., No. 04-1332, 2006 U.S. Dist. LEXIS 40620, at *17 (D. Del. May 18,

2006) (excluding expert's causation opinion where it "failed to account for any variable that may

have explained the increase in sales" of defendant's drug aside from its advertising campaign).

And, the impact such adjustments might have on Shaked's analyses are not just

academic. By way of example, Dr. Jena (again using the same data available to Shaked and also

using Shaked's "off-label" rate calculation methodology) demonstrates that accounting for even

a single confounding factor—the number of patients a physician initiated on Prezista or

Intelence—changes the outcome. Ex. F at Exs. 4a-c. Put simply, Shaked was comparing apples

(5,177 "influenced" physicians) to oranges (19,998 "non-influenced" physicians), when he

should have compared red apples (such as 619 "influenced" physicians who initiated 20 or more

patients on Prezista/Intelence with an average "off-label" rate of 30.6%) to green apples (175

"non-influenced" physicians who also initiated 20 or more patients on Prezista/Intelence with an

average "off-label" rate of 32.8%). Ex. F at Ex. 4a. Had he done so, he would have found no

meaningful difference in the average rate of "off-label" prescriptions between the two groups,

and thus no basis to make his causal claim. *See, e.g.*, *Anderson v. Westinghouse Savannah River*

Co., 406 F.3d 248, 263 (4th Cir. 2005) (excluding expert's testimony because there was "simply

too much disparity" in the comparison groups that was not controlled for in his analysis).

When asked whether he controlled for confounding factors, Shaked conceded that

he had not: "I don't think in this case it's needed . . . . It's the same drug. The same

manufacturer. . . . They are all very similar, except for one is influenced and one is

noninfluenced." Ex. B at 290:7-17. When pressed, Shaked maintained his position that there

was no need to address confounding factors because the two groups of physicians "are all

similar, except for one variable[ ]: being influenced versus noninfluenced." *Id.* at 291:2-4.

When asked what he did to ensure that the two groups were actually similar, Shaked stated:

> We didn't have to do that part. They were all physicians. All of
> them saw at least one HIV. All of them assigned at least one ARV.
> . . . all of them assign at least one . . . Prezista, Intelence. . . . So
> we didn't find any reason to believe *a priori* that they would be
> different. We analyzed it. We thought about it, analyzed it in the
> sense of, you know, logically, and elected just to take the two
> groups.

Id. at 286:5-18.[10] Any work that Shaked may have done when he "thought about it" and

"analyzed it" is notably absent, however, from his affirmative report. *Id.* at 289:23-24 (Q: "So

it's nowhere in your report." A: "No."). Other courts faced with an expert's unfounded

assumption that, as Shaked states, comparator groups "are all similar, except for one variable,"

have excluded the expert's resulting opinion as unreliable. *See, e.g.*, *Bricklayers & Trowel*

Trades Int'l Pension Fund v. Credit Suisse Sec. (USA) LLC, 752 F.3d 82, 95-96 (1st Cir. 2014)

(finding that, while the expert "had tools at his disposal . . . to guide his analysis of confounding

information," he "seemingly made a judgment call as to confounding information without any

methodological underpinning" and thus his analysis did "not satisfy the requirements of

Daubert"); *Junk v. Terminix International Co.*, 628 F.3d 439, 448 (8th Cir. 2010) ("[R]eliance on

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[10] The term *a priori* means "based on theoretical reasoning rather than actual observation." *a
priori*, *Oxford American Dictionary and Thesaurus* (2d ed. 2009).

unfounded assumptions in [expert's] comparative method created 'too great an analytical gap'

between his opinion and the data on which it relied.").

In addition to the numerous objective differences among physicians that are easily

discernable from the data produced in this case, Shaked's analyses also fail to make any effort to

address the many other subjective factors that affect a physician's prescribing decisions. As

Relators' own medical expert, Dr. Glatt, explained, "every physician takes into account their

own clinical experience when they use a drug," and exercises his or her own independent clinical

judgment, which Dr. Glatt described as:

> [T]he gestalt of a person's clinical experience, understanding of the
> literature, their assessment and review of both published data as
> well as what they may have heard at scientific meetings,
> discussions with their colleagues and their overall approach to
> treating patients with a specific medical illness.

Chuderewicz Decl., Ex. G (8/10/2020 Glatt Dep. Tr.) at 87:24-88:2, 99:20-100:4. Dr. Glatt also

agreed that it "is very important to consider the individual characteristics of a patient when one

makes a decision to use a certain medication for that patient," including such considerations as

potential drug interaction and quality of life side effects. *Id.* at 88:22-89:19.

All told, a host of factors other than so-called "influence" may have *caused*

physicians to prescribe Prezista and Intelence, and yet none of those factors have been taken into

account in any way whatsoever in Shaked's statistical analyses. In this case, Relators made the

strategic decision not to seek evidence to evaluate the reason(s) a physician prescribed a

medication for an individual HIV patient—medical records documenting a physician's decision,

statements or testimony from physicians about their decisions, or any other patient-specific

information bearing on the decision. Instead, Shaked substitutes a rudimentary statistical

analysis of data sets defined by counsel. The blatant disregard for generally accepted statistical

-19-

methodology used in assessing causation renders Shaked's opinions unreliable, and therefore his

opinions must be excluded.

      B.   **Shaked's general causation opinions relating to "off-label" promotion also should be excluded because the two variables being measured in his correlation analyses are based on unsupported assumptions that do not fit the facts of this case and result in an *unreliable* methodology.**

Even if Shaked's simple, two-variable correlation analyses were sufficient to

support causal inferences, he relied on faulty assumptions from counsel to define the two

variables being measured. When attempting to measure the "association between two variables,"

the definition of those variables will drive the analysis. *See Reference Manual on Scientific

Evidence* at 262. As Shaked confirmed, "if you change the definition, the conclusion would

change. That's correct for every model and every analysis." Ex. B at 214:9-11; *see also id.* at

178:10-12 ("I have to first get the data and then apply statistics. I cannot apply statistics and

then look for the data[.]"). Here, Shaked measured the association between receiving alleged

off-label messages or serving as a speaker (one variable) and the corresponding off-label

prescribing rates (second variable), but those measurements are unreliable because the variables

are both based on deeply flawed and unfounded assumptions provided by Relators' counsel.

      1.   <u>**First variable**</u>**: Shaked's definition of an "influenced" prescriber is based on an unsupported assumption from Relators' counsel that cannot serve as a reliable foundation for his analysis.**

Shaked's analyses attempt to measure the association between two groups of

prescribing physicians—those who are assumed to have received alleged off-label messages and

those who did not—and the alleged off-label prescribing rates of those two groups. His off-

label-promotion causation opinions rest entirely on these statistical measurements. And yet the

definition of an "influenced" prescriber (one of only two variables he attempts to measure) is

-20-

based on nothing more than an overly broad and unsupported assumption from Relators' counsel.

See In re Wellbutrin XL Antitrust Litigation, 308 F.R.D. 134, 147 (E.D. Pa. 2015) ("An

instruction from counsel is not a sound basis on which to draw an economic conclusion."). This

assumption—which is not supported by any work Shaked has done or any of the evidence in this

case—creates flawed comparator groups and is not "good grounds" upon which to base the

sweeping conclusion that Janssen's alleged improper promotion *caused* thousands of physicians

to prescribe Prezista and Intelence "off-label" for nearly a decade. *See In re TMI Litigation,* 193

F.3d 613, 663 (3d Cir. 1999) ("'Proposed testimony must be supported by appropriate validation

– i.e., good grounds, based on what is known.'") (citation omitted); *Kaseberg v. Conaco, LLC*,

No. 15-1637, 2019 U.S. Dist. LEXIS 65161, at *14 (S.D. Cal. Apr. 16, 2019) ("Proper

assumptions are particularly important to statistics, '[t]he usefulness of [which] depends on the

surrounding facts and circumstances.'") (citation omitted).

   The evidence that has been produced in this matter does not support, and at times

flatly contradicts, the assumption that *all* sales calls and speaking events contained off-label

messaging. Neither Janssen's sales call notes nor the speaker presentation documents—which

Shaked made no effort to evaluate—contain any off-label messaging. *E.g.*, Ex. B at 182:9-12,

195:3-6; *id.* at 188:20-190:4, 193:23-194:14 (confirming sample of Prezista and Intelence call

notes did not contain off-label messages and each call referenced only Prezista *or* Intelence).

While Shaked openly admits that his definition of "influenced" was given to him by counsel,

e.g., *id.* at 187:19-20 ("as I say six times at least, I rely on counsel"), he does, however, suggest

that the depositions and declarations of Janssen employees support his assumption that 100% of

Janssen's marketing contained off-label messaging. But, they do not.

   In fact, Relator Jessica Penelow herself contradicts this assumption. She testified:

"50 percent of the time I probably went off label. And 50 percent of the time I stayed on label."

Chuderewicz Decl., Ex. H (1/25/2019 Penelow Dep. Tr.) at 98:17-19. But Shaked did not make

any adjustments to his analyses even though Ms. Penelow's testimony directly contradicts the

assumption on which his definition of "influenced" is based. *See, e.g.*, Ex. B at 202:21-203:1,

204:6-9. Professor Shaked ultimately admitted that these assumptions were flawed: "As I say,

the counsel say that this is the definition that they prefer. I read the deposition. I say that doesn't

look to me really off. Again, whether it's 90 or 95 or 85, as a statistician, I'm not too

concerned." *See id.* at 211:18-22. Of the handful of other employees who provided statements

regarding alleged off-label promotion, not a single one was employed by Janssen throughout the

entire 9-year period included in Shaked's definition of "influenced," much less personally

involved in speaking with prescribers in every geographic region of the country. *See, e.g.*, Ex. A

at 13 n.24 (listing dates of employment and regions for several former employees). Even if a

few employees claimed to have regularly promoted off-label, such claims do not even come

close to providing a reliable basis from which to assume that *all* Janssen sales representatives at

all times throughout the country promoted off-label. *See United States ex rel. Wall v. Vista*

Hospice Care, Inc., No. 07-604, 2016 U.S. Dist. LEXIS 80160, at *44 (N.D. Tex. June 20, 2016)

(noting that a representative sample is "'critical to one's ability to make valid statistical

inferences about the population'" and that a sample must be "representative of the whole" to

"reliably draw . . . an inference from a sample") (citations omitted).

In addition, Shaked's definition of "influenced" also includes the baseless

assumption that the effect of the alleged improper messaging on each prescriber remained

constant throughout the entire 9-year period. Yet he made no attempt to assess the

reasonableness of that assumption by evaluating (despite having the data to do so) the length of

time between a prescriber's first contact with Janssen (first sales call received, first speaking

event attended) and the first Prezista or Intelence prescription written by that prescriber. Ex. B at

184:17-23. Nor has he conducted or reviewed any research or studies on marketing and its

impact on the audience to whom the marketing was directed. *Id.* at 44:16-20, 187:16-19.

Whether a prescribing physician was actually exposed to any alleged improper

messages (was "influenced"), let alone whether the messages had any impact, is paramount to

the question of causation. For Shaked, "as a statistician," to simply assume this to be the case in

creating a comparator group central to his analysis (particularly in the face of evidence refuting

the assumption) renders any resulting opinions based on a statistical comparison involving such a

group unreliable. *See, e.g.*, *In re TMI Litigation,* 193 F.3d at 666, 676-77 (finding "'too great a

gap between the data and the opinion proffered'" where an expert's conclusions were based on

assumptions that undoubtedly conflicted with the facts in the case).

Here, as known by counsel for Relators who provided Shaked with the factually

inaccurate assumptions, there are likely countless physicians included in Shaked's "influenced"

group who never received any alleged off-label messages from Janssen. This is admitted to be

the case for 50% of physicians visited by Relator Jessica Penelow alone, but she is just one sales

representative from one district and neither Shaked nor Dew made any effort to determine the

actual facts underlying the assumptions for the 5,177 physicians they have categorized as

"influenced." *See* Ex. A ¶ 103. The improper inclusion of such physicians as "influenced"

inappropriately distorts both comparator groups—by inaccurately including an unknown number

of physicians as "influenced" when they should have been part of the "non-influenced"

group—rendering any comparative statistical analysis as flawed as the assumption.

-23-

       2.   **<u>Second variable</u>: Shaked's artificial attribution of a patient's**
                     lifelong prescriptions to the _first_ prescriber in his calculation of
                     "off-label" prescribing rates is based on an unsupported
                     assumption from Relators' counsel that the first prescribing
                     physician is the _only_ independent decision-maker.

Relators' counsel also instructed Shaked to attribute a patient's lifelong "off-label" Prezista and Intelence prescriptions to the physician who first prescribed the medication. _E.g._, Ex. A ¶ 101. Shaked used this assumption in his calculation of "off-label" prescribing rates, which also is central to his conclusion that alleged off-label promotion by Janssen caused "influenced" physicians to prescribe Prezista and Intelence off-label at a higher rate. This means that even if a patient switched physicians, the subsequent prescriber's alleged "off-label" prescriptions were all artificially counted as prescriptions written by the first (initiating) prescriber, even though the first prescriber did not see the patient again or write any of the subsequent prescriptions. _E.g._, Ex. B at 221:3-12. This assumption and the manner in which Shaked applied it skewed the calculations in a way that artificially increased the difference between the average alleged off-label rate of the "influenced" and "non-influenced" groups of physicians.

Shaked (through Dew) calculated a physician's "off-label" rate by taking the count of "off-label" Prezista and Intelence prescriptions (numerator) divided by the count of "total" Prezista and Intelence prescriptions, which includes on- and off-label prescriptions (denominator). _E.g._, Ex. A at Ex. 26. As a result of the lifelong prescriptions assumption, _only_ an initiating prescriber is allocated any "off-label" prescriptions (numerator). Ex. C at 215:6-216:1. This means, _every_ alleged off-label prescription is _added_ to the initiating physician's count of "off-label" prescriptions (numerator) and count of "total" prescriptions (denominator), and _removed_ from the count of "off-label" prescriptions (numerator) of the non-initiating physician who actually wrote them. _Id._ at 216:3-17. As a result, physicians who did not initiate

any patients on Prezista or Intelence have alleged off-label rates of 0% (because their numerators

are *always* zero), even though these non-initiating physicians in fact wrote off-label

prescriptions. *See, e.g., id.* at 232:15-233:13. And the "off-label" prescriptions are *not removed*

from the non-initiating physicians "total" prescriptions (denominator), double-counting those

prescriptions in the initiating prescriber's and non-initiating prescriber's "total" prescriptions

(denominator). *Id.* at 235:17-236:5 ("It's using it twice; yes.") Further, although Shaked

attributes a patient's lifelong "off-label" prescriptions to the initiating prescriber, he does not

likewise attribute a patient's lifelong "on-label" prescriptions to the initiating prescriber. *Id.* at

216:19-22; *see In re: Zoloft*, 858 F.3d at 792 ("Both an expert's methodology and the application

of that methodology must be reviewed for reliability.").[11] The count of "total" prescriptions

(denominator) is therefore understated for prescribers who initiated patients "on-label."

Put simply, initiating a patient "off-label" artificially raises the initiating

prescriber's off-label rate; whereas the same assumption for "on-label" prescriptions is ignored

when it would have reduced the initiating prescriber's off-label rate. Because 83% of

"influenced" physicians were initiating prescribers, as opposed to only 34% of "non-influenced,"

the lifelong prescriptions assumption and its inconsistent application artificially and improperly

widens the gap between the average alleged "off-label" rate of the "influenced" and "non-

influenced" groups of physicians. *See* Ex. A ¶ 103 (listing total physicians in each group); Ex. B

at 325:1-4 (confirming percentage of "influenced" and "non-influenced" who never initiated).

Shaked's lifelong prescriptions assumption is based upon a complete fiction—that

only the initiating prescriber exercises any independent clinical judgment and that physicians

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[11] A visual representation of the mechanics of the off-label rate calculation acknowledged by
Dew was included in Dr. Jena's Expert Rebuttal Report. *See* Ex. F at Ex. 1.a-b.

who provide subsequent care to the patient simply accept the medical decisions of their

predecessor. *See In re TMI Litigation,* 193 F.3d at 677 ("While the [*Daubert*] analysis does not

preclude testimony merely because it may be based upon an assumption, the supporting

assumption must be sufficiently grounded in sound methodology and reasoning to allow the

conclusion it supports to clear the reliability hurdle.").

Shaked himself admittedly has no training or experience that would enable him to

reliably create or rely on such an assumption provided by counsel. *E.g.*, Ex. B at 128:18. Nor

did he undertake any effort to examine the decision-making process of subsequent prescribers or

review any of their medical records. *Id.* at 219:1-11.[12] When asked to explain the basis for this

lifelong prescriptions assumption, Shaked testified: "Makes sense based on everything that – we

talked to the lawyers. We talk to other people. The main idea is to say, let's define it as

traveling with initial. If somebody initiated it, is responsible for that." *Id.* at 219:23-220:2.

In reality, not even Relators' only medical expert, Dr. Glatt, believes that such an

assumption "[m]akes sense." Dr. Glatt testified:

> I think every . . . physician when he is caring for patients provides
> independent clinical judgment for every case. . . . So independent
> clinical judgment should be part of the care of every single patient.

Ex. G at 100:5-19. When asked specifically, if an HIV patient switches prescribers, whether the

new prescriber exercises independent clinical judgment in making treatment decisions, Dr. Glatt

testified:

> I think that every clinician should reserve the right to change their
> prior prescribing patterns or the prior prescribing patterns of the
> previous physician on each new clinical encounter. Things
> change. I and every other clinician have made changes in patient's
> regimens based on new information or what has happened since I

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[12] Dew also confirmed that the first prescription written by the initiating prescriber is all that
matters—"I'm not looking at subsequent claims and doing any reassessment." Ex. C at 176:2-4.

prescribed the previous medication. I think it is critically
important that everybody be reassessed each time you see them.
And certainly if you're seeing them after another physician and
you're now taking on a new patient[.]

Id. at 101:7-20. Shaked's assumption that the initiating prescriber "is responsible for" all

subsequent prescriptions—an assumption which flies in the face of actual medical knowledge

and experience—is nothing more than "'subjective belief or unsupported speculation'" and is

thus an unreliable basis on which to form any opinions. *See In re TMI Litigation,* 193 F.3d at

670; *see also In re: Zoloft*, 858 F.3d at 797 ("[N]onstandard techniques need to be well-

explained.").

    C.   **Shaked's specific causation opinions identifying false claims and
estimating damages resulting from Janssen's alleged improper
promotion should be excluded because they are based on unsupported
assumptions and errors that do not fit the facts of this case and result
in an *unreliable* methodology.**

Based on his general causation opinion that Janssen's alleged improper promotion

caused "influenced" physicians to prescribe higher proportions of Prezista and Intelence "off-

label," Shaked then proceeds to apply the same flawed assumptions for "influenced" physicians

and lifelong prescriptions to conclude that *every* alleged off-label prescription written by or

attributed to an initiating "influenced" physician is a false claim resulting in damages to the

government caused by Janssen. Because Shaked's "off-label" damages estimates are built on the

same unreliable foundation as his general causation opinions, they also must be excluded.

There are literally thousands of supposedly "influenced" physicians who initiated

at least one patient on Prezista or Intelence from 2006 through 2014, and, as a result, hundreds of

thousands of alleged "off-label" claims, every *single* one of which Shaked has included as

damages caused by Janssen. *See* Ex. A ¶¶ 103, 123-24; Ex. B at 325:1-4. Even assuming

Shaked's simple correlation analyses support his general causation opinions, he cannot then

-27-

reliably assume that each individual prescription written and attributed to an initiating

"influenced" physician was therefore a false claim *caused* by the alleged off-label promotion.

But that is what Shaked has done, even where the evidence indicates his assumptions are just

plain wrong. *See Perry v. Novartis Pharms. Corp.*, 564 F. Supp. 2d 452, 464 (E.D. Pa. 2008)

("Just as 'there is no fit where there is simply too great an analytical gap between the data and

the opinion offered, there is also no fit when there is too great an analytical gap between an

expert's general causation conclusion and the specific causation question the jury must

ultimately answer.") (internal citations omitted).

    According to Relators' own evidence, the group of allegedly "influenced"

physicians in fact includes those who *never* received any "off-label" messaging. Based on

Relator Jessica Penelow's testimony, at least 50% of the "off-label" prescriptions written by

initiating physicians whom she called on should be *excluded* from Shaked's damages estimate.

But they were not. Ex. B at 200:18-22 (Q: "Do you know how many influenced physicians that

you included in your analysis . . . did not receive off-label messaging from Ms. Penelow?" A: "I

assumed that all of them got it."). Again, Relator Penelow was just one representative of

Janssen's national sales force. If Shaked failed to make the necessary adjustment with the

information Relator provided, what adjustments should have been made and yet were not for the

many other sales representatives employed by Janssen throughout the 9-year period at issue

here? Shaked does not know. *See id.* at 205:19-23 (no review of information from any sales

representatives other than the few who provided testimony and declarations); *id.* at 208:2-5 (no

knowledge of the sales force size). Nor did Shaked make any adjustment based on his own

analysis that suggested half of the "influenced" physicians' alleged off-label prescriptions would

have been written regardless of any marketing from Janssen. *See* Ex. A ¶ 103 (finding average

"off-label" rate of 11.2% and 22.3% for "non-influenced" and "influenced," respectively).

Shaked's damages estimates also include prescriptions—by design—that were written by physicians who *never* received any "off-label" messaging. Shaked's lifelong prescriptions assumption—which is a complete fabrication that even Relators' own medical expert would disown—means that when a patient switches to another prescriber, that second prescriber's "off-label" prescriptions are *all* included as damages if the first prescriber was "influenced."[13] This is so, even if, as Shaked confirmed, that second prescriber *never* received any communications from Janssen. Ex. B at 221:9 ("Second one doesn't have to be influenced[.]"). The idea that a physician's decision to prescribe Prezista or Intelence to a new patient was actually *caused* by marketing to which a physician was never exposed is simply beyond belief, and is certainly not a reliable basis upon which to form an opinion on False Claims Act damages.

Finally, even the process of identifying the "off-label" claims—a process which Shaked admittedly had no knowledge or experience to provide any assistance with—was riddled with errors. Among other errors, the criteria used to identify Prezista Lipid-Neutral claims included wrong data. To identify these claims, Dew testified that he relied on a list of diagnostic codes provided by a nurse retained by Relators' counsel who supposedly had knowledge of lipid-related diagnoses, which included hyperglycemia. *See, e.g.*, Ex. C at 29:1-5. However, Relators' medical expert testified that hyperglycemia is unrelated to lipid problems. Ex. G at 200:20-24. When confronted with this error, Shaked testified that he had no recollection of whether a hyperglycemia diagnosis was used as one of the diagnostic codes to identify the

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[13] As further evidence of the completely arbitrary nature of this assumption, Relators' counsel instructed Shaked to abandon it when calculating alleged damages resulting from payments to speakers. *See, e.g.*, Ex. B at 180:3-4 ("For the speakers, doesn't have to initiate.").

alleged Prezista Lipid-Neutral claims (although it was), nor did he have any basis to agree or

disagree with Dr. Glatt. Ex. B at 125:9-15, 126:15-18. Further, Shaked had no knowledge of

how many alleged false claims and how much of his damages estimate should have been

adjusted for inappropriate inclusion of hyperglycemia. *Id.* at 127:4-11. Taken together, the

evidence of numerous faulty inputs and baseless assumptions that went into Shaked's "off-label"

damages calculations show their unreliability and therefore his corresponding opinions must be

excluded.[14]

IV.   CONCLUSION

For the foregoing reasons, the Court should exclude the expert reports of Israel

Shaked and Ian Dew in their entirety and preclude them from testifying at trial.

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[14] For alleged damages resulting from Janssen's payments to speakers, Relators' counsel asked
Shaked to assume that *all* of a speaker's Prezista and Intelence prescriptions following receipt of
his or her first speaker payment through the end of 2014, regardless of when the speaker received
his or her last speaking payment, were damages. *E.g.*, Ex. A ¶ 40. There is no economic,
medical, or even legal basis to support this novel (unreliable) assumption (a speaker's lifelong
prescriptions are damages), and thus any opinion based upon it must be excluded. *See United
States ex rel. Fesenmaier v. The Cameron-Ehlen Grp., Inc.*, No. 13-3003, 2019 U.S. Dist. LEXIS
215085, at *4 (D. Minn. Dec. 13, 2019) (government acknowledges limits on "presumptive taint
period" in a government directed FCA case based on alleged improper speaker payments).